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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/126,505	09/24/93	ATKINSON	I WU101CIP

EXAMINER: WALSH, S

ART UNIT	PAPER NUMBER
1814	8

DATE MAILED: 06/14/94

18M2/0614

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 2-14-94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ——— ~~days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☑ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-34 are pending in the application.
   Of the above, claims 4-7, 9-11, 19-22, 24-26, 33 and 34 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-3, 8, 12-18, 23, 27-32 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☑ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-32 and 34, drawn to an analog of a protein, a method for making an analog, a DNA sequence which encodes the analog, and a method for enhancing C4b or C3b cofactor activity, classified in Class 530, subclass 350.

Group II. Claim 33, drawn to a DNA sequence of claim 31 stably incorporated into the genome of a transgenic animal, classified in Class 800, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The DNA sequence of Group II's claim 33 is considered a distinct composition of matter from the DNA sequence of Group I's claim 31 because the DNA sequence of claim 33 is incorporated in and covalently bonded to genomic DNA and is therefore a portion of a larger molecule unrelated to the molecule of claim 31.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their distinct classification and recognized divergent subject matter, and because the search required for II is not required for I, restriction for examination purposes as indicated is proper.

2. Claims 1-5, 8, 11-23, 26-34 are generic to a plurality of disclosed patentably distinct species comprising analogs selected from complement regulating proteins A)containing short consensus repeats derived from a second, different complement regulating protein, B)wherein the short consensus repeats are rearranged, C)having defined amino acid substitutions in the short consensus repeats and D)consisting of as few as three short consensus repeats. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species from among A through D even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

3. Claims 1, 2, 6-9, 12-17, 21-24, 27-34 are generic to a plurality of disclosed patentably distinct species comprising an analog wherein the protein is selected from A)complement receptor one, B)decay accelerating factor, C)factor H. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species from among A through C, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be

obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

4. During a telephone conversation with Attorney Patrea L. Pabst on 1 June 1994 a provisional election was made without traverse to prosecute the invention of I, claims 1-32 and 34. Affirmation of this election must be made by applicant in responding to this Office action. Claim 33 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. In the election requirement of paragraph 2, the species of analog containing short consensus repeats derived from a second, different complement regulating protein was elected. In the election requirement of paragraph 3, the species of analog wherein the protein is complement receptor one was elected. Affirmation of these elections must be made by applicant in responding to this Office action. Claims 4-7, 9-11, 19-22, 24-26 and 34 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to non-elected species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected species are directed.

6. The Abstract of the Disclosure is objected to because the meaning of the acronym SCR should be stated in full at first use. Correction is required. See M.P.E.P. § 608.01(b).

7. The drawings are objected to for the reasons on the enclosed Form 948. Correction is required.

8. The continuing data, page 1, lines 3-6, should be updated to state the current status of the parent application.

9. The disclosure is objected to because of the following informalities: claim 1, line 7, misspells those; claim 31, line 1, misspells analog. Appropriate correction is required.

9. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-3, 8, 12-18, 23 and 27-32 are rejected under 35 U.S.C. § 101 because the invention as disclosed lacks patentable

utility. The elected subject matter claims are directed to CR1 containing short consensus repeats derived from a second, different complement regulating protein, wherein the protein has complement regulatory activity. The specification states that the analogs are useful in controlling or modulating the complement system and thus may be useful in the treatment of autoimmune diseases, the suppression of rejection of transplants, in diagnosis and the reduction in tissue damage associated with myocardial infarctions and cerebral vascular accidents, and that they may also play a role in the diagnosis of conditions associated with complement activation and immune complex formation. Disclosed diagnostic utilities require specific C3b and/or C4b binding activity, page 27, lines 25-30; claims drawn to general activity are not commensurate in scope to the disclosed specific binding requirement for utility. As the therapeutic utilities are presented with the language "may be useful", it appears that such utilities have not yet been achieved.

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use

the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10a. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention. The specification refers to Figure 2 at page 4 lines 10-21, page 10 lines 25-29, page 12 ¶2, and page 14 ¶2. It appears that the Figures 2A and 2B do not correspond to the descriptions, and that the described matter is missing.

10b. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure. Claims 16-18, 23 and 27-30 are directed to a method reciting no process steps. A process invention cannot be practiced without process steps, and the claims require appropriate amendment.

Claims 16-18, 23 and 27-30 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

10c. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, failing to adequately teach how to make and/or use the invention, i.e. failing to provide an

enabling disclosure, and failing to present a best mode of carrying out the invention. The elected subject matter claims are directed to CR1 containing short consensus repeats derived from a second, different complement regulating protein, wherein the protein has complement regulatory activity. The sequence of CR1 and the DNA encoding it are essential to produce the claimed CR1 analogs, DNA, expression system, and to practice the disclosed methods. However, the sequences are absent and thus the invention cannot be practiced. Incorporation of essential material by reference to publications is improper. The invention is broadly claimed, but it appears that only limited species of CR1 analog could be used. The claims do not require that an activity be conferred on CR1 by the substitution of SCR and thus appear to be an invitation to experiment with no way to determine if an analog is embraced by the invention. It appears that it may be intended that a new or enhanced particular activity be conferred on CR1 by the substitution. The variety of activities to be conferred on CR1 by substitution of short consensus repeat (SCR) from the distinct proteins recited by claim 2, is not commensurate in scope with the disclosure because the specification teaches how to use only those analogs that specifically bind C3b and/or C4b for diagnostic purposes. As proposed therapeutic uses are presented as speculative, it is not clear that those of ordinary skill in the art would consider the

disclosure enabling. The analog of claim 8 corresponding to the elected subject matter appears to be "CR1-4 with its first 122 amino acids (SCR1-2) SEQ ID NO:1 and 3 replaced with CR1 amino acids 497-618 (SCR 8-9) SEQ ID NO:2 and 4". The claimed analog is inadequately described by the specification because the rest of the sequence for constructing CR1-4 is missing, and because the coding sequence for the claimed DNA, also to be used in the claimed expression system, is completely absent from the disclosure. The claims do not specify which activities are to be conferred on CR1 and those of ordinary skill are thus left without guidance as to how to practice the claimed invention. Without further guidance, it would require undue experimentation to make and use all the claimed analogs having activities selected from among all complement activities. The claims may change the activity of the CR1 or keep it the same; is it intended that the SCR from the second protein will change CR1 activity?

Claims 1-3, 8, 12-18, 23 and 27-32 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

11. Claims 13, 14, 16-18, 23 and 27-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. Claims 16-18, 23 and 27-30 are incomplete because there are no process steps in the claimed method. Claims 13 and 28 are incorrect in using the term "comprises" for activities because an activity is not a structural feature that a compound can comprise. Claim 14 is ambiguous because the intended limitation of "consisting essentially of" is unclear when applied to CR1: CR1 is a polymer of about 30 SCRs but the essential function of any three is not interfered with by the presence of the others; thus a CR1 analog consisting of only three SCRs would be indistinguishable from a CR1 analog with as many as 30 SCRs when "consisting essentially of" language is used; what degree of open or closed language is intended? Claim 31 is indefinite because there is no antecedent basis for the plural "analogs" in claim 1. Claim 32 is ambiguous and confusing because an expression system is not an art accepted synonym for a composition or compound that can be transformed in to a host cell; e.g., a cell free translation system may comprise the DNA but can't be transformed into a host cell; is vector or plasmid intended? Claim 32 is ambiguous because the term "which is capable ... of expressing" suggests the DNA may not be expressed without other necessary but unnamed elements; can -- which expresses -- replace the term?

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Walsh whose telephone number is (703) 308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Walsh

Stephen Walsh
Patent Examiner
Group 1800

SW
June 12, 1994